

REMARKS

With entry of the present amendment, the application will contain claims 4-6, 15-17 and 19-22. All pending claims are under examination.

***Support***

Support for newly added claims 20-22 can be found in the specification as filed beginning on page 5 at about line 21 and ending on page 6 at about line 22.

***Allowable Subject Matter***

The Examiner is thanked for the allowance of claim 6.

***Issues Under 35 USC § 112, Second Paragraph***

The Examiner has rejected most of pending claims under the second paragraph of 35 USC § 112. It is believed that all grounds of rejection have been overcome by the present amendments.

The term "general" has been deleted from claim 4 overcoming the rejection in section (i) in the Office Action on page 2 at line 8.

The objectionable radical has been deleted from claim 4, the only claim wherein it appeared, thus overcoming the rejections in paragraph (i) on page 2, line 11, of the last Office Action.

The phrase "objected to" in paragraph (iii) on page 2, line 13, of the Office Action has been deleted.

Regarding the rejection in paragraph (iv) on page 2, line 16, of the Office Action, the Examiner is thanked for his suggestions. The claims there rejected have either been cancelled or their dependency has been corrected.

On page 2, line 19, of the Office Action, claim 13 has been cancelled, rendering moot its rejection. Regarding the rejection of claim 17 in paragraph (vi), on page 3, line 1, of the Office Action, all diseases have been cancelled. As presently amended, the claim relates to a method of blocking a potassium channel.

Claims 14 and 15 were objected to in the paragraph beginning on page 3 at line 4. Claim 14 has been cancelled rendering its rejection moot. Claim 15 has been amended to recite the specific step of administering and is now believed to be in compliance with the statute.

***Issues Under 35 USC § 101***

The paragraph beginning in the Office Action on page 3, line 8, the Examiner rejected claims 14 and 15 under 35 USC § 101 for failure to set forth steps involved in the process. Claim 14 has been cancelled rendering moot its rejection. Claim 15 has been amended to recite specific process steps and is believed to be in

full compliance with 35 USC § 101 and the cases cited by the Examiner.

***Issues Under 35 USC § 112, First Paragraph***

The rejection of selected claims under the first paragraph of 35 USC § 112 in the paragraph beginning in the Office Action on page 3, line 13, is traversed. As explained more completely below, the application as filed is fully and completely adequate to teach one skilled in the art how-to-make and how-to-use the claimed invention.

***The How-to-make Requirement Has Been Met***

Pending claims 4-6, 19 and newly added claims 20-22 are all directed to compounds. The specification as filed adequately teaches those skilled in the art how-to-make these claimed compounds. There is in fact no dispute about the adequacy of the present invention to make the compound of claim 6, which claim is allowed.

Methods of preparation of the claimed compounds are described in the specification as filed in the paragraph beginning on page 16 at line 25. A clear and lucid example is given in the specification beginning on page 23, at about line 6. This example shows how to produce the compound of allowed claim 6. Regarding

this ground of rejection, claim 4 is representative. In rejected claim 4, the recitation of "A" and "B" merely gives the residue of the reactants employed to produce the claimed compounds in accordance with the two-step process exemplified on page 23, at about line 9 and at about line 23. One skilled in the art will readily perceive the modification of the reactants necessary to produce other compounds within the scope of that claim, once a choice has been made for the moiety "A" and the moiety "B".

The Examiner's attention is respectfully invited to the fact that R<sup>5</sup>, R<sup>6</sup>, R<sup>7</sup> and R<sup>8</sup> are all optional substituents on fused rings remote from the reaction site. There is no reason to believe that the presence of any of the substituents would in any way effect the reaction.

In summary, once one skilled in the art chooses the moieties "A" and "B", the specification teaches one skilled in the art how to combine them in a reaction not likely to be affected by any of the optional substituents R<sup>5</sup>, R<sup>6</sup>, R<sup>7</sup> and/or R<sup>8</sup>.

***The How-to-use Requirement Has Been Met***

The statute requires that the specification explain how-to-use the present invention. The compounds of the present invention are used in pharmaceutical compositions. The synthesis of these

compositions is described in the specification beginning on page 17 at about line 24 and ending on page 18 at about line 23.

Administering of the compounds of the present invention is explained in the paragraph beginning on page 18 at about line 24. The doses of the compounds of the present invention is given on page 21, beginning at about line 35. Modes of therapy employing the claimed compounds are described in detail on page 22 from about line 9 to about line 37.

Clearly, the specification as filed gives more than adequate information to explain to one skilled in the art how-to-use the claimed compounds and furthermore how to do so without any undue experimentation.

#### ***Response to the Examiner's Arguments***

Nothing the learned Examiner said in support of the rejection in any way modifies the above facts and explanations. Nevertheless, it is useful to consider the arguments raised by the Examiner in support of the rejection under the first paragraph of 35 USC § 112. The Examiner argues that "there is only one compound made" (Office Action, page 3, line 17). The facts are that the single synthesis example, beginning on page 23 at about line 6, shows how-to-make the preferred compound of allowed patentable claim 6. It is too well known to require the citation of authority

that examples are not even required in applications. This example has a single representative example. The issue is whether the specification as a whole teaches how-to-make and how-to-use the claimed invention. Clearly, this specification does as explained above.

In further support of the rejection, the Examiner argues that the compound of allowed claim 6 "...does NOT give a reasonable assurance that all, or substantially all of them, are useful" (last Office Action, page 3, line 18). Usefulness or utility under 35 USC § 101 is not at issue. Reasonable assurance has been given as explained above.

In further support of the rejection, the Examiner argues that "the claims are not drawn in terms of a recognized genus..." (Office Action page 3, line 19). It is respectfully submitted that Formula II, in representative claim 4, is a genus defining novel compounds that everyone skilled in the art will recognize. In the alternative, claiming of a recognized genus is not necessary to meet either the how-to-make or the how-to-use requirement of 35 USC § 112.

The Examiner argues further that "there no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful" (Office Action, page 4, line

1). The reason is that all claims, drawn in their present form, comply with the statute.

The Examiner further argues that "Applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful...". This unsupported allegation has nothing to do with whether or not the how-to-make and how-to-use requirements of 35 USC § 112 have been met. These requirements have been met as explained above.

The paragraph beginning in the last Office Action on page 4 at about line 5, the Examiner relies on In re Surrey 151 USPQ 724. That case, decided almost four decades ago, fails to make a distinction between rejections under 35 USC § 112 and 35 USC § 101. As dissenting Judge Smith said in that case, "the requirements of § 101 and § 112 should not be confused" (151 USPQ 732).

In the last Office Action in the paragraph beginning on page 4, at line 13, the Examiner relies on a quotation from the Supreme Court case of Brenner v. Manson, which quotation appears at 148 USPQ 696. The Examiner's reliance on Brenner v. Manson is misplaced since that case dealt with utility under 35 USC § 101. A rejection on this statutory ground is pending only against claim 15 and has been adequately dealt with above. The quoted dicta in In re Diedrich, 138 USPQ 130 does not compel any different conclusion.

**Utility Under 35 USC § 101**

Only claim 15 has been rejected in this case for lack of utility under 35 USC § 101. Should the Examiner apply this section of the statute against other pending claims, any such rejection should be non-final, giving the Applicant an opportunity to respond and amend as a matter of right.

CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact David R. Murphy (Reg. No. 22,751) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.




Appl. No. 10/029,168

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Gerald M. Murphy, Jr., #28,977

  
GMM/DRM/enm  
2815-0187P

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000